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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,948	03/03/2004	Warren S. Taranow	TNW-10002/29	4130
25006	7590	11/19/2007	EXAMINER	
GIFFORD, KRASS, SPRINKLE, ANDERSON & CITKOWSKI, P.C			PATEL, TARLA R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/791,948	TARANOW, WARREN S.
	Examiner	Art Unit
	Tarla R. Patel	3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 October 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 3-9, 19, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 3-9, 19, 21 and 22 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 October 2007 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 10/19/07.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/07 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/15/07. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "fin, boot or shoe" as claimed in claim 19, "male and female connector" as claimed in claim 4 and "rigid structure includes a cast" as

claimed in claim 22, "an intermediate layer/ perforated layer disposed between inner surface of the band and the skin of a wearer" as claimed in claims 6 and 7 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required

corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "306" has been used to designate both port and band, reference character "204" has been used to designate both sleeve, membrane and material; reference character "704" has been used to designate both brace member and element; reference character "806" has been used to designate both foot portion and ground contacting portion; and reference character "1110" has been used to designate both band and layer. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The claim 4 recites “male and female connector” however this limitation does not have support in original specification.

6. The disclosure is objected to because of the following informalities: The original specification discloses “rigid element 604”, “rigid brace member”, “rigid membranes 224,226”, and “rigid members 324,326”. The multiple uses to rigid structure is not consistent and the examiner fails to understand what structure applicant is specifically referring to whenever these various terms are used.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 21-22, 3-9 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim 21 and all of its dependent claims recite a “rigid structure”; this limitation is not disclosed in the original specification and does not shown in figures. Based on the description as originally filed, it is not clear what exact structures encompass the amended claims “rigid structure” as set forth in the amended and new claims. Thus it is unclear which embodiment shows the claimed subject matter. Is it directed to figure 7? Figure 7 appears to show a rigid portion or structure that extends around and past the end portion of the leg as now claimed in newly presented claim 21.

9. Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The amended claim(s) now contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claims 6 and 7 recite “an intermediate layer/perforated layer disposed between the inner surface of

the band and the skin of a wearer" is not disclosed in the original specification and not shown in figures; based on disclosure it is not clear where an intermediate layer/ perforated layer is disposed and how it is disposed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 3,5-7, are 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler et al. (6,397,400) in view of McDavid, III (5,797,865).

Hassler et al. discloses a flexible band (35, combination of 36-39) adapted to encircle a calf portion (see fig 4 shows 36-39 encircling the human leg) of a human leg extending entirely through the band, the leg terminating in an end portion not covered by the band (see fig 4), the band having an inner surface (inside of the splint device/band 35) spaced apart from the skin of a wearer (see fig 4) and an outer surface (outer side of splint device/band 35) with opposing side portions (see fig 4) and a port (valve device

31) facilitating evacuation of the space so that the inner surface of the band makes intimate, slip free contact with the skin (as described in column 5 line 54- column 6 line 3 and column 5 lines 17-30, discloses a valve device 31 comprising a handle 32, which is connected to a valve body 33 and counter to the action of a valve spring 34, which allows an evacuation of interior space obviously will create intimate contact, obviously create slip-free contact with the skin) and a structure/foot loops (45) coupled to the side portion of the band, the structure including a portion that extends around and past the end portion of the leg, thereby transferring loads to the band and calf portion as opposed to the end portion of the leg (see fig 4, element 45 is extending around and past the end portion of the leg as shown dotted line, however it is silent to what material it is made of)
Fastener also can be of hook and loop type fastener (43,44 column 6 lines 4-10). The device also further discloses an intermediate layer (natural fibers and synthetic fibers, column 2 lines 1-11) between the sleeve and the skin of the wearer, which is made by non-woven and porous textured sheet or perforated (natural fibers and synthetic fibers are inherently is porous) materials.

Hassler does not disclose that foot loop/a structure extends around and past the end portion of the leg is rigid structure because it is silent to material it is made of.

However McDavid, III teaches a light weight ankle restraint having made of the plastic material which provide optimum balance between stiffness and impact strength (column 7 line 44-column 8 line 9). At the time of invention was made, it would have been obvious to one having ordinary skill in art to use the plastic material to make the foot loop/ a structure of Hassler, as taught by McDavid to better support user leg with device.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler and McDavid, III further in view of Nauert (6,402,711).

Hassler and McDavid, III substantially disclose the invention, see rejection to claims 3,5-7, are 21 above; however Hassler and McDavid, III do not disclose that brace has a hinge attached to the sleeve using a male-female mechanical connector.

However Nauert discloses knee brace including an operating hinge with an upper (43) or male and lower (49) or female mechanical connector. At the time of the invention was made, it would have been obvious design choice to modify the hinge of Hassler and McDavid, III by substituting the male-

female connector to hinge part, as taught by Nauert to provide upper and lower connector, since substitution of parts which provide the same function, in this case that of connecting the sleeve and orthotic via a hinge connection and limiting the angular displacement of the device, would be within the level of ordinary skill in the art.

13. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler and McDavid, III further in view of Detty (5,472,413).

Hassler and McDavid, III substantially disclose the invention, see rejection to claims 3,5-7, are 21 above; however Hassler and McDavid, III do not disclose that brace includes a thermal-insulating layer inside the sleeve. However Detty discloses a knee and elbow brace is made having a thermal-insulating layer. At the time of the invention was made, it would have been obvious to one skilled in art to make the layer of the Hassler and McDavid's device to include the thermal insulating material, which is taught by Detty to maintain an elevated temperature at the joint of the user's body.

14. Claims 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassler and McDavid, III further in view of Hydorn (2,545,146).

Hassler and McDavid, III substantially disclose the invention, see rejection to claims 3,5-7, are 21 above; however Hassler and McDavid, III do not disclose that rigid structure include a cast, a shoe, boot, or fin.

However, Hydorn teaches an artificial limb (1, obviously it is a cast for the limb) is rigid (column 1 lines 14-17) and upper leg section having a boot (2, column 1 lines 49-51). At the time of the invention was made, it would have been obvious to one having ordinary skill in art to use the teaching of rigid structure/ artificial limb to invention of Hassler and McDavid, as taught by Hydorn to have leg support for supporting weight of user, while the device is in use.

Response to Arguments

15. Applicant's arguments with respect to claims 21-22, 3-9 and 19 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Habermeyer et al. (5,399,152) discloses an apparatus for treating fractures in extremities by deformable and evacuable vacuum-tight cushions having at least one valve.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tarla R. Patel whose telephone number is 571-272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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